

REMARKS

By way of summary, Claims 1-30 were pending in this application prior to this Request for Continued Examination. In the outstanding Office Action of October 4, 2007, the Examiner again rejected Claims 1 and 9-10 under 35 U.S.C. §102(a) as being anticipated by Gifford, III (U.S. Pub. No. 2004/0267191), and rejected Claims 2-8 and 11-30 under 35 U.S.C. §103(a) as being unpatentable over Gifford in view of six other references. In this amendment in the Request for Continued Examination, Claims 12, 13, 20, 27 and 28 have been amended, Claims 16 and 26 have been canceled, and Claims 31-35 have been added.

I. Claim Amendments

In this Amendment, Claims 12, 13, 20, 27 and 28 have been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

II. § 102(e) Claim Rejections

The Examiner has rejected Claims 1 and 9-10 under 35 U.S.C. § 102(e) as being anticipated by Gifford. For the reasons set forth below, Applicant respectfully traverses these rejections.

A. Priority Date of Gifford

As discussed in Applicant's response filed June 8, 2007, Applicant reserves the right to argue at a later date that Gifford does not qualify as prior art under 35 U.S.C. § 102(e) to the extent that none of the three provisional applications to which Gifford claims priority describe and enable an embodiment corresponding to Figures 23A-23B and paragraph 98 of Gifford. MPEP §2121.01 discusses the standard for the use of prior art in rejections where operability is in question: "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a

reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003).

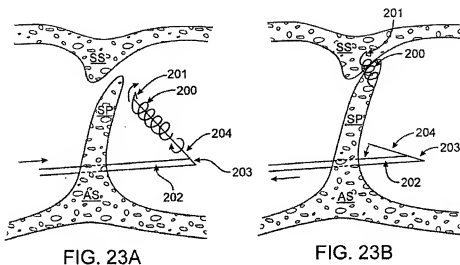
Applicant directs the Examiner to MPEP § 2136.03 section III, which states:

The 35 U.S.C. 102(e) critical reference date of a U.S. patent or U.S. application publications and certain international application publications entitled to the benefit of the filing date of a provisional application under 35 U.S.C. 119(e) is the filing date of the provisional application with certain exceptions **if the provisional application(s) properly supports the subject matter relied upon to make the rejection in compliance with 35 U.S.C. 112, first paragraph. See MPEP § 706.02(f)(1), examples 5 to 9. (emphasis added).**

Without enabling disclosure from the provisional applications, Gifford's filing date of March 26, 2004 comes after the present Application filing date of February 20, 2004. Applicant raised this issue in the previous Office Action Response received on June 8, 2007, however the Final Office Action does not address this issue.

B. Independent Claim 1, and Dependent Claims 9 and 10, are not Anticipated nor Rendered Obvious by Gifford

Applicant disagrees with the Examiner's characterization of the Gifford reference. Gifford discloses methods and apparatus for treatment of a patent foramen ovale (PFO) with embodiments using a retractable abrasive needle from a catheter, advancing the needle through the PFO and/or tissue adjacent to the PFO, and retracting the needle relative to the PFO to abrade at least a portion of the tissue. Gifford Abstract. The Examiner cites one particular embodiment of Gifford's needle with reference to figures 23A and 23B and paragraph [0098]: these are reproduced here for the Examiner's convenience:



At paragraph [0098], Gifford states (with Examiner's characterizations in parentheses):

"...a PFO a spiral needle 200 ("coil") may be applied to tissue adjacent the PFO to close the PFO, from a position within the left atrium. As shown in FIG. 23A, in one embodiment, a catheter 202 ("outer catheter") is delivered through the atrial septum AS, with spiral needle 200 ("coil") and a retractable delivery arm 204 ("elongate body") retracted within catheter 202 ("outer catheter"). Once a distal portion of catheter 202 ("outer catheter") is positioned in the left atrium, delivery arm 204 ("elongate body") may be extended from catheter 202 ("outer catheter") about a universal joint 203. Catheter 202 ("outer catheter") may then be turned, twisted or torqued to drive spiral needle 200 ("coil") off of delivery arm 204 ("elongate body") and into tissue adjacent the PFO. In one embodiment, as shown, spiral needle 200 ("coil") is driven into and through septum primum SP tissue and into septum secundum SS tissue to bring the two tissues together. **A hook or barb 201 on spiral needle 200 ("coil") helps hold needle 200 ("coil") in place within tissue.** As shown in FIG. 23B, when spiral needle 200 ("coil") is in place, it pulls together septum primum SP and septum secundum SS. Retractable delivery arm 204 ("elongate body") is then retracted within catheter 202 ("outer catheter"), and catheter 202 ("outer catheter") is withdrawn."

The Applicant does not agree with the Examiner's characterization of the Gifford barb 201 as a tissue piercing structure as claimed in Claim 1. See Office Action at page 11. Claim 1 recites, in part, "releasing the coil from the elongate body and withdrawing the tissue piercing structure from the septa of the patent foramen ovale." The Examiner is characterizing the Gifford barb 201 as a part of a characterized coil as well as a tissue piercing structure, yet Claim 1 recites, in part, "releasing the coil from the elongate body and withdrawing the tissue piercing structure from the septa of the patent foramen ovale." The Gifford barb 201 is not withdrawn

from the septa of the patent foramen ovale, thus the barb 201 can not be the tissue piercing structure as claimed in Claim 1.

The figures of Gifford show a barb 201 at the distal end of the spiral needle 200, but that is the only structure described which is shown to pierce any tissue. As described in Gifford's specification and as shown in Gifford's figures, the distal end of the delivery arm 204 does not pierce any tissue in the septum primum SP tissue or the septum secundum SS tissue. Instead, the catheter 202 turns, twists or torques the spiral needle 200 off the delivery arm 204. Once the needle 200 is delivered, the delivery arm 204 is retracted back into the catheter 202 and the catheter 202 is withdrawn, leaving what would appear to be a hole in or below the septum primum (SP) where the catheter 202 is withdrawn.

Furthermore, in contrast to the disclosure and teachings of Gifford, Claim 1 recites, in part, "advancing the tissue piercing structure and the coil through the septa of the patent foramen ovale, wherein both the tissue piercing structure and the coil extend into the septum primum and the septum secundum." As discussed above, Gifford does not have a separate tissue piercing structure that extends in the septum primum and septum secundum. Instead, Gifford drives a barb 201 which is part of the distal end of the spiral needle 200 into the PFO. Nowhere does Gifford disclose that part of the elongate member or delivery arm 204 pierces, enters, or comes into contact with tissue while it is extended in the left atrium or retracted within the catheter 200. Furthermore, the delivery arm 204 does not "extend in the septum primum and the septum secundum." Accordingly, Applicant respectfully submits that independent Claim 1 is not anticipated nor rendered obvious by Gifford and respectfully requests that the anticipation rejections based on Gifford be withdrawn.

Claims 9 and 10 depend from Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to amended Claim 1, Applicant respectfully submits that Claims 9 and 10 are patentable over Gifford. Claims 9 and 10 also are patentable over Gifford in view of the additional limitations recited in each of the claims. In particular, Claim 10 recites delivering the tissue piercing structure and the coil first through the septum secundum and then through the septum primum. The delivery shown in Gifford places the spiral needle 200 first through the septum primum and then through the septum secundum. Therefore, Applicant

respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 1, 9 and 10 based on Gifford.

III. § 103(a) Claim Rejections

From an initial standpoint, all of the Examiner's 35 U.S.C. § 103 claim rejections include Gifford. As expressed above, Applicant disagrees with the Examiner's application of Gifford as prior art to the extent that the provisional applications to which Gifford claims priority do not describe and enable an embodiment corresponding to Figures 23A-23B and paragraph 98 of Gifford.

A. All Claim Rejections Fail to Provide Proper Graham Factual Inquiries and Fail to Articulate Findings under the KSR Examination Guidelines

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* ("Examination Guidelines"), which were published in the Federal Register Vol. 72, No. 195 (Docket PTO-P-2007-0031) on October 10, 2007, clarify the Supreme Court's decision on *KSR Int'l. v. Teleflex, Inc.* with regard to the issue of obviousness under 35 U.S.C. §103(a) in relation to prior art. *KSR Int'l. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 2007). Applicant submits that the outstanding Office Action fails to satisfy the Examiner's burden in establishing an obviousness rejection.

Under the Examination Guidelines, and as reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in *Graham v. John Deere Co.* Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

The Examination Guidelines confirms the role of Patent Office personnel as factfinders:

When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

72 Fed. Reg. 57527 (Oct. 10, 2007).

The Examination Guidelines further provide that “Once the Graham factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.” *Id.* “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* at 57528-57529 (internal citations omitted). Under the Examination Guidelines, a rejection must offer specific support for the following rationales Examiners may use to show obviousness:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Id. at 57529.

For example, in order to reject a claim on rationale (G) above, Office personnel must first resolve the Graham factual inquiries, and then must articulate the following:

- (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- (2) a finding that there was reasonable expectation of success; and
- (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

Id. at 57534. The rationale to support a conclusion that the claim would have been obvious is that “a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.” *Id.* If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. *Id.* An explicit suggestion to combine the prior art is not necessary, but “[i]n such situations, the proper question is whether the ordinary artisan possess knowledge and skills rendering him capable of combining the prior art references.” *Id.* (internal citations omitted).

The October 4, 2007 Office Action fails to set forth the level of ordinary skill in the pertinent art, or who qualifies as one of ordinary skill in the field. Applicant submits that without such a finding, the Examiner’s combinations are improper, as the Examiner has not established that the references proposed by the combinations would be known to one of ordinary skill in the art, nor that one of ordinary skill would have the requisite knowledge and ability to make the desired combinations. Moreover, the Examiner has failed articulate specific rationales for the proposed combinations of references, and has failed to provide explicit explanations supporting the obviousness rejections. Rather, the Examiner makes merely conclusory statements regarding the combinability of the cited prior art references, without identifying the knowledge one skilled in the art would possess, what modifications the skilled person would need to make to combine the prior art references, and whether that skilled person would have a reasonable expectation of success. Accordingly, Applicant submits that the Examiner’s obviousness rejections are improper. More specific details relating to these missing inquiries and missing articulated findings are discussed in more detail below, along with Applicant’s reasoned statements explaining why Applicant’s claims are nonobvious over the cited art.

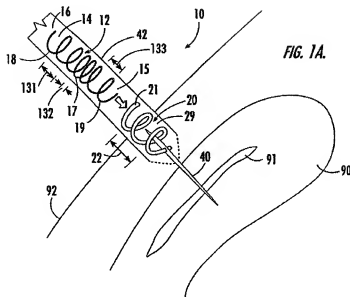
B. Claims 2 and 11-19 are not Rendered Obvious over Gifford in view of Pierson, III (“Pierson”) (U.S. 6,663,633)

The outstanding Office Action rejected Claims 2 and 11-19 under 35 U.S.C. §103(a) as being unpatentable over Gifford in view of Pierson. Applicant asserts that one skilled in the art would not have combined Gifford with Pierson, and that the Examiner has not articulated a proper rationale why one skilled in the art would have combined the prior art elements in the manner claimed by the Applicant.

1. **Gifford and Pierson Are Not Properly Combinable**

Applicant submits that one skilled in the art would not look to Pierson to modify a PFO method as in Gifford, because Pierson is directed to orthopedic procedures for fixing soft tissue tears (such as tears in the menisci of the knee) or bone fractures reduction. Pierson col. 1, ll. 8-16, and 23. The Examiner has made no factual findings that one skilled in the art of PFO treatment would have knowledge of the Pierson systems and methods relating to orthopedic procedures, and Applicant submits that it would be beyond the knowledge of one skilled in the relevant PFO art to utilize the teachings of Pierson and modify them to produced Applicant's claimed invention with any reasonable expectation of success. For example, with respect to Claim 12, Gifford teaches a delivery arm 204 that carries a single spiral needle 200, and one skilled in the art would not understand from Pierson or his own knowledge how to modify Gifford in an operable way to deliver a plurality of coils using the same delivery arm. The PFO environment is much different from the orthopedic environment, and it goes beyond just a combination of known elements to produce the claimed invention.

Further, the Office Action has erred substantively as to the factual findings and continues to mischaracterize a distal opening in an elongate member. The Office Action asserts Gifford discloses the claimed invention "except for the elongate body having an opening near its **distal end**." Office Action at 3 (emphasis added). Claim 2 recites, in part, "the elongate body includes an opening near its distal end." The Examiner "considers the opening to be apparent in FIG. 1A of Pierson, where the distal end of coil 20 extends through a hole or opening in the delivery member 40." See Office Action p. 12, point 16. However, FIG. 1A shows what might be an opening in the guide needle 40 at the needle's **proximal end**, not its distal end:



Pierson col. 7, ll. 29-35. Accordingly, Pierson does not overcome the deficiencies of Gifford.

The Office Action goes on to state “it would have been obvious to one of ordinary skill in art to modify Gifford with this feature since it allows secure and effective engagement of the coil with the delivery member which avoids undesirable or inadvertent disengagement of deployment of the coil into tissue.” Office Action at 12. The Office Action also states that combining Gifford with Pierson would have been obvious “since it was known in the art an opening would allow the coil element to effectively engage with the elongate body without the use of a separate fastening or attachment device.” Office Action at 3-4. While the Examiner’s statements may explain the advantages of the proposed combination of Gifford and Pierson, nowhere does the Examiner articulate why such a modification would be obvious to one skilled in the art, especially in view of the Examination Guidelines as explained above. Elsewhere in the Office Action the Examiner asserts that Gifford and Pierson are combinable for the proposition of withdrawing the tissue piercing structure 40 of Pierson from the septa, and for providing a second coil to the septa of the PFO. Office Action at 4. The Examiner’s rationale is similarly conclusory, stating that these combinations would have been obvious “in order to provide a more secure closure of the *sp* and *ss* by covering more surface area of the tissue,” without actually explaining why one skilled in the art would have found it obvious to make the specific combination. *Id.*

Applicant submits that one skilled in the art would not have any reasonable expectation of success in making the proposed combination in view of the fact that Pierson is in a different field of endeavor than Gifford, and the extensive modifications that would need to be made in order for the proposed combination to be operable. For example, neither the references themselves nor the knowledge of one skilled in the art reveal how the catheter 202 or delivery arm 204 in Gifford would be modified to provide the opening asserted by the Examiner to be present in Pierson, or how the system in Pierson could be adapted to be delivered to the PFO as taught in Gifford with a catheter that passes through the septum primum, and a delivery arm that turns back toward the PFO. For these reasons, Applicant submits that the Examiner's obviousness rejection over Gifford and Pierson is improper, and the rejections of the claims based on this combination be withdrawn.

2. Claim 12 Recites Additional Features Not Taught or Suggested by the Cited Art

Claim 12 as amended recites, inter alia, a method comprising releasably engaging a plurality of discrete implantable coils with a single delivery device, the single delivery device comprising a tissue piercing structure, the plurality of discrete implantable coils comprising a distal most coil releasably engaging the tissue piercing structure and one or more proximal coils positioned axially along the single delivery device. Moreover, Claim 12 recites advancing the tissue piercing structure with the distal most coil at least partially through the septa of the patent foramen ovale at a first location to secure the septum primum and septum secundum together; retracting the tissue piercing structure proximally to engage an additional coil without removing the tissue piercing structure from the body of the patient; and advancing the tissue piercing structure with the additional coil at least partially through the septa of the patent foramen ovale at a second location to secure the septum primum and septum secundum together.

The combination of Gifford in view of Pierson does not disclose, teach or suggest these claimed features. For example, neither Gifford nor Pierson disclose or suggest retracting a tissue piercing structure to engage an additional coil without removing the tissue piercing structure from the body of the patient. Accordingly, Applicant submits that Claim 12 is allowable over the cited references.

3. **Claim 2, 11 and 13-15 and 17-19 Recite A Unique Combination of Features Not Taught or Suggested by the Cited Art**

Dependent Claims 2 and 11 depend from amended Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1 as well as the lack of any explained rationale to combine Gifford in view of Pierson, Applicant respectfully submits that Claims 2 and 11 are patentable over Gifford in view of Pierson. Claims 2 and 11 are also are patentable over Gifford in view of Pierson in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 2 and 11 based on Gifford in view of Pierson.

Dependent Claims 13-15 and 17-19 depend from Claim 12 and further define the invention of Claim 12. For at least the reasons set forth above with respect to amended Claim 12, Applicant respectfully submit that Claims 13-15 and 17-19 are patentable over Gifford in view of Pierson. Claims 13-15 and 17-19 are also are patentable over Gifford in view of Pierson in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 13-15 and 17-19 based on Gifford in view of Pierson.

C. **Dependent Claims 3 and 4 are Not Rendered Obvious over Gifford and Pierson in view of Johnson (U.S. 6,485,504)**

The outstanding Office Action rejected Claims 3 and 4 under 35 U.S.C. §103(a) as being unpatentable over Gifford and Pierson in view of Johnson. Dependent Claims 3 and 4 depend from amended Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1 as well as the lack of any explained rationale to combine Gifford in view of Pierson, Applicant respectfully submit that Claims 3 and 4 are patentable over Gifford and Pierson in view of Johnson.

Moreover, Applicant submits that the Examiner's reliance on Johnson is similarly deficient in that the Examiner makes only conclusory statements regarding the result of combining Johnson with Gifford/Pierson, without explaining the level of ordinary skill in the art or why one skilled in the art would have found the combination to be obvious. Applicant submits that as the teachings provided by Johnson are in the field of bone healing, it would be beyond the knowledge of one skill in the art of PFO treatment to understand and modify the

Johnson teachings to apply to the proposed Gifford/Pierson combination, and one skilled in the art would not have any reasonable expectation of success in making the proposed combination.

Claims 3 and 4 are also are patentable over Gifford and Pierson in view of Johnson in view of the additional limitations recited in each of the claims. For example, as described in Applicant's Office Action response of December 5, 2006, the pushing rod 108 of Johnson does not come in contact with the proximal end of the coil as asserted by the Examiner. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 3 and 4 based on Gifford and Pierson in view of Johnson.

D. Dependent Claims 5-7 are not Rendered Obvious over Gifford in view of Laufer (U.S. Pub. 2004/0193194)

The outstanding Office Action rejected Claims 5-7 under 35 U.S.C. §103(a) as being unpatentable over Gifford in view of Laufer. Dependent Claims 5-7 depend from amended Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1, Applicant respectfully submit that Claims 5-7 are patentable over Gifford in view of Laufer.

Moreover, Applicant submits that the Examiner's proposed obviousness rejection based on Gifford and Laufer is deficient in that the Examiner makes only conclusory statements regarding providing a loading collar "in order to protect and secure the proximal end of the coil and advance it towards the tissue while avoiding the need for another instrument to release the coil from the proximal end into the tissue." Office Action at 7. Again, nowhere does the Examiner establish what is the level of skill in the art, nor make any specific findings explaining why one skilled in the art would have found this combination to be obvious. Applicant submits that as the teachings in Laufer are in the field of tissue reconfiguration particularly for gastroesophageal reflux disease, it would be beyond the knowledge of one skill in the art of PFO treatment to understand and modify the Laufer to apply to system and method of Gifford, and one skilled in the art would not have any reasonable expectation of success in making the proposed combination.

Claims 5-7 are also are patentable over Gifford in view of Laufer in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests

the Examiner to reconsider and withdraw the rejection of Claims 5-7 based on Gifford in view of Laufer.

E. Dependent Claim 8 is not Rendered Obvious over Gifford and Laufer in view of Johnson

The outstanding Office Action rejected Claim 8 under 35 U.S.C. §103(a) as being unpatentable over Gifford and Laufer in view of Johnson. Dependent Claim 8 depends from amended Claim 1 and further defines the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1, Applicant respectfully submit that Claim 8 is patentable over Gifford and Laufer in view of Johnson. Applicant also submits that the obviousness rejections based on Laufer and Johnson are improper in view of the discussion above with respect to Claims 3 and 4 and 5-7. Claim 8 is also patentable over Gifford and Laufer in view of Johnson in view of the additional limitations recited in its claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claim 8 based on Gifford and Laufer in view of Johnson.

F. Independent Claim 20 and Dependent Claims 21, 26 and 29 are not Rendered Obvious over Gifford in view of Kobayashi (U.S. 6,375,671)

The outstanding Office Action rejected Claims 20, 21, 26 and 29 under 35 U.S.C. §103(a) as being unpatentable over Gifford in view of Kobayashi. For the reasons articulated below, Applicant respectfully traverses these rejections.

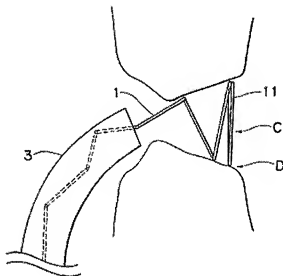
1. Gifford and Kobayashi Are Not Properly Combinable

Applicant asserts that one skilled in the art would not have found a reason to combine Gifford with Kobayashi, and that the Examiner has not explicitly articulated sufficient reason why one skilled in the art would have combined the prior art elements in the manner claimed by the Applicant. The Examiner has made no factual findings as to the level of ordinary skill in the art, and has not provided sufficient explanation as to why one skilled in the art would find such a combination obvious. The Examiner's reasons for combining Gifford with Kobayashi are conclusory, saying that the combination would have been obvious "in order to effectively narrow the coil in diameter to fit the hole in the tissue" (Office Action at 8), and because "it would allow the surgeon to manipulate or control the coil the surgeon [sic], which facilitates careful delivery into tissue." Office Action at 13. Yet nowhere does the Examiner articulate what knowledge one

skilled in the art would possess, nor how one skilled in the art would have any reasonable expectation of success to incorporate the necessary modifications to make the proposed combination operable.

Applicant submits that one skilled in the art would not look to Kobayashi to modify a PFO method as in Gifford, because Kobayashi is directed to closure devices with relatively large-sized circular portions for closing open septal defects. Kobayashi Abstract and all Figures.

Fig. 6



Kobayashi does not refer to a PFO, which as Gifford describes, has a flap and a patent channel. Gifford p. 1, para. [0004]. Instead, Kobayashi is directed to open holes in the septa which use “relatively large-sized circular portions” to occlude the septal defects, in which “the flap of tissue is missing” as is described in Gifford p. 1, para. [0004]. In order to have the Gifford method and device operable, the spiral needle must secure one flap into parallel tissue: “the spiral needle 200 (“coil”) is driven into and through septum primum SP tissue and into septum secundum SS tissue to bring the two tissues together.” Gifford p. 10, para. [0098].

Applicant submits that the modification proposed by the Examiner involves more than just ordinary skill or common sense in order to make the modification operable. Specifically, Gifford teaches a single spiral needle 200, that is driven into and through septum primum SP tissue and into septum secundum SS tissue to bring the two tissues together, and one skilled in the art would not understand from Kobayashi or his own knowledge how to modify Gifford in an

operable way to attach a flap to overlapping tissue that is not present in an open septal defect. The application of a spiral needle to an open septal defect would not be likely to be therapeutic and would likely increase damage to the heart.

2. Gifford and Kobayashi Combined Do Not Disclose Claim 20

Further, even if the references were combined, Gifford and Kobayashi fail to produce the claimed embodiment of Claim 20, as amended. Applicant disagrees with the Examiner's characterization of what Gifford and Kobayashi teach. For example, the Examiner states "Gifford discloses the claimed device, including a loading portion 204 adapted to releasably engage a distal end of a coil 200." Office Action at 8. Gifford does not disclose a loading portion. Object 204 is a deployment arm and Gifford provides no description as to how, or even if, the deployment arm 204 is attached to the spiral needle 200. Gifford states that "Catheter 202 ("outer catheter") may then be turned, twisted or torqued to drive spiral needle 200 ("coil") off of delivery arm 204 ("elongate body") and into tissue adjacent the PFO." There is no disclosure of a loading portion as claimed in the Applicant's claim.

The Examiner also states that Gifford discloses "a distal structure (distal end of coil 200) adapted to releasably engage a distal end of the coil 200 using a tissue piercing structure that is integral with the tissue piercing structure." Office Action at 8-9. The Applicant is unable to understand how the characterized "tissue piercing structure"—which, as described above, is not disclosed in Gifford—is attached to the spiral needle or how the Examiner characterizes it as engaging the distal end of the coil 200. It is not clear how Gifford uses "a tissue piercing structure that is integral with the tissue piercing structure." Office Action at 8-9.

3. Kobayashi Does Not Disclose A Tissue Piercing Structure

In response to Applicant's previous argument with regard to Claim 20, page 12 of the Office Action states that "one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." Applicant's previous argument, stating that "Kobayashi does not disclose any tissue piercing structures," was in response to the Examiner's incorrect suggestion that Kobayashi teaches a piercing structure. Applicant submits that without the teaching of a tissue piercing structure in Kobayashi, the Examiner's rationale for combining Kobayashi with Gifford is flawed, and that the teachings of Kobayashi do not provide sufficient motivation for justifying a combination with Gifford.

The Examiner further stated at page 12 of the October 4, 2007 Office Action that Gifford is meant to be combined with Pierson and Kobayashi. However, Claim 20 was not rejected under any combination with Pierson, and it is not apparent how the Applicant should respond as no details are provided on that combination of references in the Office Action.

4. Claims 20-21, 26 and 29 Recite A Unique Combination of Features Not Taught or Suggested by the Cited Art

Applicant respectfully submits that independent Claim 20 is not rendered obvious by Gifford in view of Kobayashi and respectfully requests that the rejections based on Gifford in view of Kobayashi be withdrawn. Dependent Claims 21, 26 and 29 depend from Claim 20 and further define the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20, Applicant respectfully submit that Claims 21, 26 and 29 are patentable over Gifford in view of Kobayashi. Claims 21, 26 and 29 are also are patentable over Gifford in view of Kobayashi in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 20, 21, 26 and 29 based on Gifford in view of Kobayashi.

G.. Dependent Claims 22 and 23 are Not Rendered Obvious over Gifford and Kobayashi in view of Kay (U.S. 5,662,683)

The outstanding Office Action rejected Claims 22 and 23 under 35 U.S.C. §103(a) as being unpatentable over Gifford and Kobayashi in view of Kay. Dependent Claims 22 and 23 depend from amended Claim 20 and further define the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20, Applicant respectfully submit that Claims 22 and 23 are patentable over Gifford and Kobayashi in view of Kay.

Moreover, Applicant submits that the Examiner's reliance on Kay to prove obviousness is deficient in that the Examiner makes only conclusory statements regarding providing a loading portion comprising a slot "in order for the surgeon to apply a force to the coil, which facilitates its delivery to tissue." Office Action at 9. Nowhere does the Examiner indicate what is the level of skill in the art, nor explain a specific rationale for why one skilled in the art would have found this combination to be obvious. Applicant submits that one skilled in the art, based on his own skill or the knowledge provided by prior art known to him, would not have understood how to

modify the very different disclosures provided in Gifford, Kobayashi and Kay to produce Applicant's claimed invention.

Claims 22 and 23 are also are patentable over Gifford and Kobayashi in view of Kay in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 22 and 23 based on Gifford and Kobayashi in view of Kay.

H. Dependent Claim 23 is not Rendered Obvious over Gifford, Kobayashi and Kay in view of Pierson

The outstanding Office Action rejected Claim 23 under 35 U.S.C. §103(a) as being unpatentable over Gifford, Kobayashi and Kay in view of Pierson. Dependent Claim 23 depends from amended Claim 20 and further defines the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20, Applicant respectfully submit that Claims 22 and 23 are patentable over Gifford, Kobayashi and Kay in view of Pierson.

Moreover, for the reasons discussed above with respect to Claims 2 and 11-19, 20-21, 26 and 29, and 22-23, Applicant submits that the Examiner's proposed combination of the four references to prove obviousness is improper. With respect to the addition of Pierson to the proposed combination, Applicant submits that for the same reasons as discussed above, the Examiner's reliance on Pierson for obviousness is unsupported by factual findings or sufficient specific explanation, and that one skilled in the art would not understand from Pierson how to make the necessary modifications to produce the claimed device, or have a reasonable expectation of success in doing so.

Claim 23 is also are patentable over Gifford, Kobayashi and Kay in view of Pierson in view of the additional limitations recited in Claim 23. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claim 23.

I. Dependent Claims 24-25 is not Rendered Obvious over Gifford, Kobayashi in view of Laufer

The outstanding Office Action rejected Claims 24 and 25 under 35 U.S.C. §103(a) as being unpatentable over Gifford and Kobayashi in view of Laufer. Dependent Claims 24 and 25 depend from amended Claim 20 and further define the invention of Claim 20. For at least the

reasons set forth above with respect to Claim 20, Applicant respectfully submit that Claims 24 and 25 are patentable over Gifford and Kobayashi in view of Laufer.

Moreover, Applicant submits that the Examiner's reliance on Laufer to prove obviousness is deficient in that the Examiner makes only conclusory statements regarding providing a loading collar "since it was known in the art that loading collars abut against the tissue to stabilize the surgical site and facilitate deployment of devices that engage with the tissue." Office Action at 10. As discussed above, nowhere does the Examiner indicate what is the level of skill in the art, nor explain a specific rationale for why one skilled in the art would have found this combination to be obvious. Applicant submits that as the teachings in Laufer are in the field of tissue reconfiguration particularly for gastroesophageal reflux disease, it would be beyond the knowledge of one skill in the art of PFO treatment to understand and modify the Laufer to apply to the combined system and method of Gifford/Kobayashi, and one skilled in the art would not have a reasonable expectation of success in making the proposed combination.

Claims 24 and 25 are also are patentable over Gifford and Kobayashi in view of Laufer in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 24 and 25.

J. Dependent Claims 27 and 28 are Not Rendered Obvious over Gifford and Kobayashi in view of Bolduc (U.S. 5,582,616)

The outstanding Office Action rejected Claims 27 and 28 under 35 U.S.C. §103(a) as being unpatentable over Gifford and Kobayashi in view of Bolduc. Dependent Claims 27 and 28 depend from amended Claim 20 and further define the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20, Applicant respectfully submit that Claims 27 and 28 are patentable over Gifford and Pierson in view of Johnson.

Moreover, Applicant submits that the Examiner's reliance on Bolduc to prove obviousness is deficient in that the Examiner makes only conclusory statements regarding providing "a tang on either or both ends of the coil to Gifford and Kobayashi in order to attach the coil to a delivery device so that it can be effectively secured before being attached to a tissue." Office Action at 11. Nowhere does the Examiner indicate what is the level of skill in the art, nor explain a specific rationale for why one skilled in the art would have found this combination to be obvious. Applicant submits that one skilled in the art, based on his own skill

or the knowledge provided by prior art known to him, would not have understood how to modify the devices provided by Gifford and Kobayashi in order to make the proposed combination with Bolduc, or have a reasonable expectation of success in doing so.

Claims 27 and 28 are also are patentable over Gifford and Kobayashi in view of Bolduc in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 27 and 28 based on Gifford and Kobayashi in view of Bolduc.

K. Dependent Claim 30 is not Rendered Obvious over Gifford and Kobayashi in view of Pierson

The outstanding Office Action rejected Claim 30 under 35 U.S.C. §103(a) as being unpatentable over Gifford and in view of Pierson. Dependent Claim 30 depends from amended Claim 20 and further defines the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20, Applicant respectfully submit that Claim 30 is patentable over Gifford and Kobayashi in view of Pierson.

Moreover, for the reasons discussed above with respect to Claims 2 and 11-19, Applicant submits that the Examiner's proposed reliance on Pierson to prove obviousness is improper. As discussed above, the Examiner's reliance on Pierson for obviousness is unsupported by factual findings or sufficient specific explanation, and that one skilled in the art would not understand from Pierson how or have a reasonable expectation of success to make the necessary modifications to produce the claimed device.

Claim 30 is also are patentable over Gifford and Kobayashi in view of Pierson in view of the additional limitations recited in Claim 30. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claim 30.

IV. New Claims

Applicant has added new Claims 31-35 in this Amendment. Applicant respectfully submits that the added claims read upon the previously prosecuted invention without introducing any new matter. Applicant also respectfully submits that the added claims are patentable over the cited art for reasons similar to the ones discussed above. Accordingly, Applicant respectfully

submits that the newly added claims are in condition for allowance, and Applicant respectfully requests allowance of the same.

V. Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

| Serial Number | Title | Filed | Matter Reference |
|---------------|----------------------------------------------------------------------------------------|------------|------------------|
| 11/584,828 | TISSUE OPENING OCCLUDER | 10/23/2006 | EV3.062DV1 |
| 11/607237 | TISSUE OPENING OCCLUDER | 11/30/2006 | EV3.062DV2 |
| 11/927448 | TISSUE OPENING OCCLUDER | 10/29/2007 | EV3.062C1 |
| 10/419412 | SEPTAL DEFECT OCCLUDER | 4/21/2003 | EV3.058CPC1 |
| 10/227773 | DEFECT OCCLUDER RELEASE ASSEMBLY AND METHOD | 8/26/2002 | EV3.059C1 |
| 10/930321 | RETRIEVABLE SEPTAL DEFECT CLOSURE DEVICE | 8/31/2004 | EV3.067C1 |
| 10/972635 | PATENT FORAMEN OVALE CLOSURE SYSTEM | 10/25/2004 | EV3.079A |
| 10/771845 | PATENT FORAMEN OVALE CLOSURE SYSTEM | 2/4/2004 | MVMDINC.019A |
| 10/841880 | DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE USING A COUNTERTRACTION ELEMENT | 5/7/2004 | MVMDINC.068A |

VII. Conclusion

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or prior art, Applicant is not conceding in this application that

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Filed : **February 20, 2004**

previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, she is invited to telephone Applicant's attorney of record so that extended prosecution of this application may be avoided.

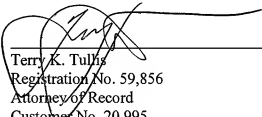
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 01-62-2008

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